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Document Processing Center (TS-790)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
401 M Street., S.W.
Washington, D.C. 20460
Attn: Section 8(e) Coordinator (CAP Agreement)

Dear Coordinator:

8ECAP-0025

On behalf of the Regulatee and pursuant to Unit II B.1.b. and Unit II C of the 6/28/91CAP Agreement, E.I. Du Pont de Nemours and Co. hereby submits (*in triplicate*) the attached studies. Submission of this information is voluntary and is occasioned by unilateral changes in EPA's standard as to what EPA now considers as reportable information. Regulatee's submission of information is made solely in response to the new EPA §8(e) reporting standards and is not an admission: (1) of TSCA violation or liability; (2) that Regulatee's activities with the study compounds reasonably support a conclusion of substantial health or environmental risk or (3) that the studies themselves reasonably support a conclusion of substantial health or environmental risk.

The "Reporting Guide" creates new TSCA 8(e) reporting criteria which were not previously announced by EPA in its 1978 Statement of Interpretation and Enforcement Policy, 43 Fed Reg 11110 (March 16, 1978). The "Reporting Guide states criteria which expands upon and conflicts with the 1978 Statement of Interpretation. Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" raises significant due processes issues and clouds the appropriate reporting standard by which regulated persons can assure TSCA Section 8(e) compliance.

For Regulatee,

Mark H. Christman
Counsel
Legal D-7158
1007 Market Street
Wilmington, DE 19898
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UC
1/26/93

ATTACHMENT 1

Submission of information is made under the 6/28/91 CAP Agreement, Unit II. This submission is made voluntarily and is occasioned by recent changes in EPA's TSCA §8(e) reporting standard; such changes made, for the first time in 1991 and 1992 without prior notice and in violation of Regulatee's constitutional due process rights. Regulatee's submission of information under this changed standard is not a waiver of its due process rights; an admission of TSCA violation or liability, or an admission that Regulatee's activities with the study compounds reasonably support a conclusion of substantial risk to health or to the environment. Regulatee has historically relied in good faith upon the 1978 Statement of Interpretation and Enforcement Policy criteria for determining whether study information is reportable under TSCA §8(e), 43 Fed Reg 11110 (March 16, 1978). EPA has not, to date, amended this Statement of Interpretation.

After CAP registration, EPA provided the Regulatee the June 1, 1991 "TSCA Section 8(e) Reporting Guide". This "Guide" has been further amended by EPA, EPA letter, April 10, 1992. EPA has not indicated that the "Reporting Guide" or the April 1992 amendment supersedes the 1978 Statement of Interpretation. The "Reporting Guide" and April 1992 amendment substantively lowers the Statement of Interpretation 's TSCA §8(e) reporting standard[2]. This is particularly troublesome as the "Reporting Guide" states criteria, applied retroactively, which expands upon and conflicts with the Statement of Interpretation.[3] Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" and the April 1992 amendment clouds the appropriate standard by which regulated persons must assess information for purposes of TSCA §8(e).

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[2]In sharp contrast to the Agency's 1977 and 1978 actions to soliciting public comment on the proposed and final §8(e) Policy, EPA has unilaterally pronounced §8(e) substantive reporting criteria in the 1991 Section 8(e) Guide without public notice and comment. See 42 Fed Reg 45362 (9/9/77), "Notification of Substantial Risk under Section 8(e): Proposed Guidance".

[3]A comparison of the 1978 Statement of Interpretation and the 1992 "Reporting Guide" is a appended.

Throughout the CAP, EPA has mischaracterized the 1991 guidance as reflecting "longstanding" EPA policy concerning the standards by which toxicity information should be reviewed for purposes of §8(e) compliance. Regulatee recognizes that experience with the 1978 Statement of Interpretation may cause a review of its criteri. Regulatee supports and has no objection to the Agency's amending reporting criteria *provided that* such amendment is not applied to the regulated community in an unfair way. However, with the unilateral announcement of the CAP under the auspices of an OCM enforcement proceeding, EPA has wrought a terrific unfairness since much of the criteria EPA has espoused in the June 1991 Reporting Guide and in the Agency's April 2, 1992 amendment is new criteria which does not.exist in the 1978 Statement of Interpretation and Enforcement Policy.

The following examples of new criteria contained in the "Reporting Guide" that is not contained in the Statement of Interpretation follow:

o even though EPA expressly disclaims each "status report" as being preliminary evaluations that should not be regarded as final EPA policy or intent[4], the "Reporting Guide" gives the "status reports" great weight as "sound and adequate basis" from which to determine mandatory reporting obligations. ("Guide" at page 20).

o the "Reporting Guide" contains a matrix that establishes new numerical reporting "cutoff" concentrations for acute lethality information ("Guide" at p. 31). Neither this matrix nor the cutoff values therein are contained in the Statement of Interpretation. The regulated community was not made aware of these cutoff values prior to issuance of the "Reporting Guide" in June, 1991.

othe "Reporting Guide" states new specific definitional criteria with which the Agency, for the first time, defines as 'distinguishable neurotoxicological effects'; such criteria/guidance not expressed in the 1978 Statement of Interpretation.[5];

othe "Reporting Guide" provides new review/ reporting criteria for irritation and sensitization studies; such criteria not previously found in the 1978 Statement of Interpretation/Enforcement Policy.

othe "Reporting Guide" publicizes certain EPA Q/A criteria issued to the Monsanto Co. in 1989 which are not in the Statement of Interpretation; have never been published in the Federal Register or distributed by the EPA to the Regulatee. Such Q/A establishes new reporting criteria not previously found in the 1978 Statement of Interpretation/Enforcement Policy .

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[4]The 'status reports' address the significance, if any, of particular information reported to the Agency, rather than stating EPA's interpretation of §8(e) reporting criteria. In the infrequent instances in which the status reports contain discussion of reportability, the analysis is invariably quite limited, without substantial supporting scientific or legal rationale.

[5] *See, e.g,* 10/2/91 letter from Du Pont to EPA regarding the definition of 'serious and prolonged effects' as this term may relate to transient anesthetic effects observed at lethal levels; 10/1/91 letter from the American Petroleum Institute to EPA regarding clarification of the Reporting Guide criteria.

In discharging its responsibilities, an administrative agency must give the regulated community fair and adequate warning to as what constitutes noncompliance for which penalties may be assessed.

> Among the myriad applications of the due process clause is the fundamental principle that statutes and regulations which purport to govern conduct must give an adequate warning of what they command or forbid.... Even a regulation which governs purely economic or commercial activities, if its violation can engender penalties, must be so framed as to provide a constitutionally adequate warning to those whose activities are governed.

Diebold, Inc. v. Marshall, 585 F.2d 1327, 1335-36 (D.C. Cir. 1978). *See also*, Rollins Environemntal Services (NJ) Inc. v. U.S. Environmental Protection Agency, 937 F. 2d 649 (D.C. Cir. 1991).

While neither the are rules, This principle has been applied to hold that agency 'clarification', such as the Statement of Interpretation, the "Reporting Guide" nor the April 1992 amendments will not applied retroactively.

> ...a federal court will not retroactively apply an unforeseeable interpretation of an administrative regulation to the detriment of a regulated party on the theory that the post hoc interpretation asserted by the Agency is generally consistent with the policies underlying the Agency's regulatory program, when the semantic meaning of the regulations, as previously drafted and construed by the appropriate agency, does not support the interpretation which that agency urges upon the court.

Standard Oil Co. v. Federal Energy Administration, 453 F. Supp. 203, 240 (N.D. Ohio 1978), aff'd sub nom. Standard Oil Co. v. Department of Energy, 596 F.2d 1029 (Em. App. 1978):

The 1978 Statement of Interpretation does not provide adequate notice of, and indeed conflicts with, the Agency's current position at §8(e) requires reporting of all 'positive' toxicological findings without regard to an assessment of their relevance to human health. In accordance with the statute, EPA's 1978 Statement of Interpretation requires the regulated community to use scientific judgment to evaluate the significance of toxicological findings and to determining whether they reasonably support a conclusion of a substantial risk. Part V of the Statement of Interpretation urges persons to consider "the fact or probability" of an effect's occurrence. Similarly, the 1978 Statement of Interpretation stresses that an animal study is reportable only when "it contains reliable evidence ascribing the effect to the chemical." 43 Fed Reg. at 11112. Moreover, EPA's Statement of Interpretation defines the substantiality of risk as a function of both the seriousness of the effect and the probability of its occurrence. 43 Fed Reg 11110 (1978). Earlier Agency interpretation also emphasized the "substantial" nature of a §8(e) determination. See 42 Fed Reg 45362, 45363

(1977). [Section 8(e) findings require "extraordinary exposure to a chemical substance...which critically imperil human health or the environment"].

The recently issued "Reporting Guide" and April 1992 Amendment guidance requires reporting beyond and inconsistent with that required by the Statement of Interpretation. Given the statute and the Statement of Interpretation's explicit focus on substantial human or environmental risk, whether a substance poses a "substantial risk" of injury requires the application of scientific judgment to the available data on a case-by-case basis.

If an overall weight-of-evidence analysis indicates that this classification is unwarranted, reporting should be unnecessary under §8(e) because the available data will not "reasonably support the conclusion" that the chemical presents a substantial risk of serious adverse consequences to human health.

Neither the legislative history of §8(e) nor the plain meaning of the statute support EPA's recent lowering of the reporting threshold that TSCA §8(e) was intended to be a sweeping information gathering mechanism. In introducing the new version of the toxic substances legislation, Representative Eckhart included for the record discussion of the specific changes from the version of H. R. 10318 reported by the Consumer Protection and Finance Subcommittee in December 1975. One of these changes was to modify the standard for reporting under §8(e). The standard in the House version was changed from "causes or contributes to an unreasonable risk" to "causes or significantly contributes to a substantial risk". This particular change was one of several made in TSCA §8 to avoid placing an undue burden on the regulated community. The final changes to focus the scope of Section 8(e) were made in the version reported by the Conference Committee.

The word "substantial" means "considerable in importance, value, degree, amount or extent". Therefore, as generally understood, a "substantial risk" is one which will affect a considerable number of people or portion of the environment, will cause serious injury and is based on reasonably sound scientific analysis or data. Support for the interpretation can be found in a similar provision in the Consumer Product Safety Act. Section 15 of the CPSA defines a "substantial product hazard" to be:

> "a product defect which because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise, creates a substantial risk of injury to the public."

Similarly, EPA has interpreted the word 'substantial' as a quantitative measurement. Thus, a 'substantial risk' is a risk that can be quantified, *See*, 56 Fed Reg 32292, 32297 (7/15/91). Finally, since information pertinent to the exposure of humans or the environment to chemical substances or mixtures may be obtained by EPA through Sections 8(a) and 8(d) regardless of the degree of potential risk, §8(e) has specialized function. Consequently, information subject to §8(e) reporting should be of a type which would lead a reasonable man to conclude that some type action was required immediately to prevent injury to health or the environment.

Attachment

Comparison:

Reporting triggers found in the 1978 "Statement of Interpretation/ Enforcement Policy",43 Fed Reg 11110 (3/16/78) and the June 1991 *Section 8(e) Guide.*

TEST TYPE	1978 POLICY CRITERIA EXIST?	New 1991 GUIDE CRITERIA EXIST?
ACUTE LETHALITY		
Oral	N}	Y}
Dermal	N}	Y}
Inhalation (Vapors)	}[6]	}[7]
aerosol	N}	Y}
dusts/ particles	N}	Y}
SKIN IRRITATION	N	Y[8]
SKIN SENSITIZATION (ANIMALS)	N	Y[9]
EYE IRRITATION	N	Y[10]
SUBCHRONIC (ORAL/DERMAL/INHALATION)	N	Y[11]
REPRODUCTION STUDY	N	Y[12]
DEVELOPMENTAL TOX	Y[13]	Y[14]

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[6]43 Fed Reg at 11114, comment 14:

"This policy statements directs the reporitng of specifiec effects when unknown to the Administrator. Many routine tests are based on a knowledge of toxicity associated with a chemicalL unknown effects occurring during such a range test may have to be reported if they are those of concern tot he Agency and if the information meets the criteria set forth in Parts V and VII."

[7]Guide at pp.22, 29-31.

[8]Guide at pp-34-36.

[9]Guide at pp-34-36.

[10]Guide at pp-34-36.

[11]Guide at pp-22; 36-37.

[12]Guide at pp-22

[13]43 Fed Reg at 11112

"Birth Defects" listed.

[14]Guide at pp-22

NEUROTOXICITY	N	Y[15]
CARCINOGENICITY	Y[16]	Y[17]
MUTAGENICITY		
In Vitro	Y}[18]	Y} [19]
In Vivo	Y}	Y}
ENVIRONMENTAL		
Bioaccumulation	Y}	N
Bioconcentration	Y}[20]	N
Oct/water Part. Coeff.	Y}	N
Acute Fish	N	N
Acute Daphnia	N	N
Subchronic Fish	N	N
Subchronic Daphnia	N	N
Chronic Fish	N	N
AVIAN		
Acute	N	N
Reproductive	N	N
Reprodcutive	N	N

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[15] Guide at pp-23; 33-34.

[16] 43 Fed Reg at 11112
"Cancer" listed

[17] Guide at pp-21.

[18] 43 Fed Reg at 11112; 11115 at Comment 15
"Mutagenicity" listed/ *in vivo* vs *invitro* discussed; discussion of "Ames test".

[19] Guide at pp-23.

[20] 43 Fed Reg at 11112; 11115 at Comment 16.

CAS# 382-21-8
Chem: Perfluoroisobutylene, hexafluoropropylene; carbonyl fluoride
Title: Toxicity Studies of Pyrolysis Products of Fluorinated Polymers
Date: 5/4/56
Summary of Effects: Perisobutylene 6 Hr ALC = 0.5 ppm

TOXICITY STUDIES OF PYROLYSIS PRODUCTS OF FLUORINATED POLYMERS

Medical Research Project No. MR-297

Report No. 18-56

Earlier studies from the Haskell Laboratory on the toxicity of the pyrolysis products of "Teflon" polytetrafluoroethylene resin were reported in 1952 and 1954 (1, 2). The present studies are concerned with: (1) a more extensive investigation of two of the pyrolysis products studied previously, i.e., perfluoroisobutylene and hexafluoropropylene; (2) a preliminary investigation of the toxicity of carbonyl fluoride; (3) investigation of the toxicity on pyrolysis of various experimental and commercial "Teflon" samples; and (4) investigation of the toxicity on pyrolysis of two competitive fluorinated polymers.

In order to define more accurately the toxicological hazards associated with the pyrolysis of the polymers, animals were exposed to the inhalation of air passed over fabricated strips of polymer heated over a temperature range of 200° to 350° C. and under conditions of both high and low humidity. Fabricated samples rather than powder, were tested since information concerning the hazards involved in the use rather than in the fabrication was desired. For purposes of comparison, two experimental and two competitive polymers were also tested. A listing of the samples used in this study follows:

A. Gases

Compound	Sample No.	Haskell No.
Perfluoroisobutylene	E.S. 8200	1279
Hexafluoropropylene	3227-24	1278
Carbonyl fluoride	NB-9083-1061 and 10711	1277

B. Polymers

I. Commercial "Teflon" Samples

(a) Granular Polymers

(1) "Teflon"-1 B No. 3846, N.B. 3227-20, 30, Haskell No. 1306. "This sample was compression molded (N.B. 4485-12, sheet 207) from "Teflon"-1 (Order 03-55-5) at 2000 psi, sintered for 1 hr at 400°C, the specific gravity was 2.0694."

(2) "Teflon"-2 (Powder) B 3893A, NB 3227-21, Haskell No. 1276. "One pound of "Teflon"-1 (Lot 17293) powder sent 6/11/54 for study of toxicity of alcoholic extract."

(3) "Teflon"-5 B 3934, Haskell No. 1380. "Five mil shaved tape from Continental-Diamond Fibre Company (Lot 90E-UT2)."

(b) Dispersion Polymers

(1) "Teflon"-6 B 3850B, NB 3227-28, Haskell No. 1307. (TE 3086, Lot 20022) NB 4587-41. "Lubricated with 17% BM & P naphtha and paste extruded to 2" pipe with 60 mil wall thickness. Presintered 350°C for one minute, postsintered at 390°C for 35 minutes."

(2) TE-3109 (Lot R50038) B 3893-J, NB 3227-18, Haskell No. 1309. "FST Polymer which was shipped unlubricated from the plant, lubricated with 17% BM & P naphtha and paste extruded to 2" pipe with a 60 mil wall thickness. Sintered at 360°C for one minute."

(3) "Teflon" Covered Wire (Loose Fit) B 3893E, NB 3227-31, Haskell No. 1321-1. "TE-3109 on silver plated copper wire. The polymer was paste extruded using white oil at the Jennings Machine Company."

(4) "Teflon" Covered Wire (Tight Fit) B 3893-F, NB 3227-54, Haskell No. 1321-2. Otherwise same as above sample. "Two spools (4540-3A start and 4540-3D start) were sent to the Haskell Laboratory."

(5) "Fluorofilm" B 3893-G, NB 3227-63, Haskell No. 1370. "Manufactured by the Dielectrix Company by casting "Teflon"-30. Film thickness was 0.5 mil."

II. Experimental Polymers

(1) Poly FEP B 3893-H, NB 3227-22, Haskell No. 1308. (TFE/HFP Copolymers) Blend 7. "This sample was supplied with the understanding that Poly FEP will not be disclosed outside the du Pont Company without the prior consent from the Polychemicals Department. The sample was prepared by sintering at 340°C for 15 minutes and then compression molded at 360°C."

(2) "Teflon" Telomerized with Hydrogen B 3893-I, NB 3227-106, Haskell No. 1399. "Compression molded 60 mil films were prepared from THA Run 2024. (Standard Specific Gravity 2.2720.) This polymer exhibits thermal stability comparable to "Teflon"-1."

III. Competitive Polymers

(1) "Fluon" B 3893-H, NB 3227-92, Haskell No. 1393. "Manufactured by Imperial Chemical Industries. Compression molded at 2000 psi, sintered at 380°C for 1.25 hrs, annealed to 250°C to yield 63 mil film."

(2) "Kel-F" B 3093-C, NB 3227-29, Haskell No. 1323. "High density (Lot 2746-H). This sample was compression molded at 280°C for 5 minutes to yield 65 mil film."

Procedure for Gas Inhalation Tests

The test gas was mixed with air in a carboy and then passed into a bell jar containing two male albino rats. The concentrations were calculated from the flow rates of the test gas and of air, and are, therefore, nominal.

Results of the Gas Inhalation Tests

The results of these tests are summarized in Tables 1 and 2.

Perfluoroisobutylene at a concentration of 0.5 ppm for six hours was lethal for rats, while 0.3 ppm for six hours was not lethal. The lethal Ct (product of concentration and exposure x time), 3 ppm-hours, agrees with the previously reported lethal Ct, 0.76 ppm x 4 hours (letter to K.C.Brinker, June 23, 1954). Subacute exposure to 0.1 ppm, six hours per day for ten days, was not lethal. There was no cumulative toxicity that could be determined by clinical observation, weight gain, gross and micropathological examination, and organ weights.

Hexafluoropropylene at a concentration of 735 ppm for six hours was lethal for rats, while 600 ppm for six hours was not lethal. Subacute exposure to 220 ppm for six hours per day was lethal to two of the four rats exposed after four exposures. The remaining two rats survived ten exposures, but were found to have enlarged kidneys, as well as tubular nephritis at autopsy.

Carbonyl fluoride -- The lethal Ct could not be determined due to the small amount of this gas that was available. A concentration of 5 ppm for two and one-half hours was not lethal and no gross or microscopic pathology was found at autopsy, either one or eight days after exposure. Hence carbonyl fluoride is less toxic than perfluoroisobutylene.

Apparatus for Exposure of Rats to Polymer Pyrolysis Products

The apparatus is shown diagrammatically in Figure 1. The polymer samples were heated in a glass tube (J) by means of a multiple unit furnace (I). The temperature of the furnace was controlled within ± 2°C by means of a "Micromax" indicating controller-potentiometer system (L). An iron-constantan thermocouple was inserted through the furnace so that it was in contact with the glass heating tube (J).

The dimensions of the glass heating tube were 2 in. (O.D.) by 16 in. The tube was designed so that air had to pass over the test material before it could pass out through the center exit tube. Standard taper, glass joints were used between the heating tube and the bell jar (K). The volume of the bell jar used in all the acute exposures except Runs No. 58, 61 and 66 (Table III) was 4.25 lit. For Runs No. 58, 61, and 66 and for the subacute exposures a 20 lit bell jar was used. The pyrolysis units were obtained through the courtesy of K. C. Brinker of the Polychemicals Department Research Division.

Air at the rate of 4 lit/min was first passed through a drying column (B) and then through a water vaporizer (F). The air stream was then divided equally between two separate pyrolysis units and bell jars. A motor-driven syringe (D) was used to deliver water at a constant rate to the vaporizer. The amounts of water added to the air stream (0.085 or 0.028 ml/min) correspond to relative humidities of 95 and 30 per cent respectively at 25° C.

With an air flow rate of 2 lit/min or less, the air temperature inside the heating tube was within ± 2°C of the wall temperature, from the end of the tube up to seven inches from the air inlet. The air temperature inside the bell jar was about 27°C when the furnace temperature was 350°C.

Procedure for Exposure of Rats to Polymer Pyrolysis Products

The polymer samples were cut into strips whose approximate dimensions were 160 x 10 x 1.5 mm. Up to four strips were used depending on the surface area required. Each polymer strip was twisted so that only a minimum of its surface could come in contact with the heating tube wall or with other strips.

The heating tubes were first brought to the desired temperatures. The air temperature inside the tubes was checked by a second iron-constantan thermocouple before and after each run. The polymer samples were then inserted in the heating tubes which were connected to the bell jar containing the animals. The air streams were then connected to the two heating tubes. The surface temperature of the polymer strips reached equilibrium in about 15 minutes. The exposure period, however, was considered to have started at the instant the air streams were connected to the heating tubes.

Results of the Acute Exposures to Polymer Pyrolysis Products

The results of all the acute exposures are summarized in Table 3. An effort was made to establish the relationship between the surface area of polymer, the length of the exposure period, and the toxicity at each of the temperatures used (200°, 250°, 300° and 350°C). Six hours and 16,000 sq mm were considered the practical upper limits for the exposure period and surface area respectively.

Initially all the surviving rats were kept for a ten-day observation period. It was discovered, however, that all the deaths occurred within twenty-four hours as a result of pulmonary edema and congestion. It was considered likely that if pulmonary edema had developed in the surviving rats, it would have disappeared before ten days. For these reasons, therefore, the observation period was subsequently reduced to twenty-four hours.

The results show that at 200° and 250°C none of the polymer samples produced any toxic effects.

Reference to Table 3 will show that the order of toxicological hazard of the three principal "Teflon" samples tested is TE-3109 (FST), "Teflon"-6, "Teflon"-1. "Kel-F" was found to present a greater toxicological hazard than "Teflon"-1, "Teflon"-6 or TE-3109 (FST). "Fluorofilm", "Fluon", FST (H_2), and Poly FEP were found to present no greater toxicological hazards than "Teflon"-1 and lesser hazards than "Teflon"-6 and TE-3109 (FST).

The toxicity produced by the polymers did not appear to be influenced to any great extent by the relative humidity. This can readily be seen in the case of TE-3109 (FST) where in addition to an R.H. of 95 and 30 per cent, dry air was used (Runs No. 57, 60, 64 and 65).

Procedure for Subacute Exposure of Rats to Polymer Pyrolysis Products

These exposures were carried out at 250°C and 95 per cent R.H. Rats were exposed seven hours per day, five days per week, for a total of thirty days. The "Fluorofilm" sample (150 x 680 mm) was rolled up into a cylinder and tied loosely by means of a glass fiber string. Two pieces of "Teflon"-5 Shaved Tape (each 5.1 x 200 cm) were rolled up and tied in the same manner as the "Fluorofilm." The same samples were used for all thirty exposures.

Since it was established during the acute exposures that the temperature of the bell jar was about 27°C, it was not considered necessary for the control rats to be exposed to air that had passed through a heated tube. The air in this case was humidified by passing through a fritted glass bubbler tube maintained at a constant temperature of 25°C. The R.H. was determined to be about 95 per cent.

Results of Subacute Exposure of Rats to Polymer Pyrolysis Products

The results of these tests are summarized in Table 4. It can be seen that no cumulative toxicity that could be detected by clinical signs, growth rate (Figure 2), mortality, gross and micropathological examination and organ weights was produced by either "Teflon"-5 or "Fluorofilm."

Approximately 50 per cent of the total weight loss in the "Teflon"-5 sample was observed after the first exposure. Thereafter, the weight loss was fairly uniform. In the case of the "Fluorofilm" sample, the entire weight loss occurred during the first exposure, and no weight loss was observed during subsequent exposures.

Results of Attempts to Filter Out Lethal Factor from Pyrolysis Products of "Teflon"

The results of these experiments are summarized in Table 3 (Runs No. 92 to 96 inclusive). The same apparatus was used for these experiments as was used for the acute exposures, except for the filters. In Run No. 92 it can be seen that when the air from the pyrolysis unit was bubbled through 200 ml of distilled water, the lethal factor was not removed. The total

amount of fluoride found in the bubbler (1.0 mg) was almost exactly the same as the amount found in similar experiments carried out by the Research Division of the Polychemicals Department.

Selts filter disks (cellulose-asbestos, 60 mm diameter and 5 mm thick) were placed between two glass funnels (55 mm O.D.). The two funnels were connected by means of a Gooch rubber. The stem of one of the funnels was inserted through a rubber stopper which was then inserted in the end of the glass tube connecting the heating tube to the bell jar. The filter was thus inside the bell jar. It can be seen that the filters with an average pore size of 0.1, 2 or 5 microns, removed the lethal factor from the air stream when the "Teflon" samples were heated at 350°C (Runs No. 93, 94 and 95). Due to the thickness of the filter, it is difficult to conclude whether the lethal factor was removed by filtration or adsorption. However, when the "Teflon" sample was heated at 430-500°C, the 0.1 micron filter failed to remove the lethal factor (Run No. 96).

Inhalation Toxicity of Alcoholic Extract of "Teflon"-1

In the first experiment 600 gm of "Teflon"-1 powder were divided into three equal portions. Each portion was extracted for five minutes by the same sample of absolute ethyl alcohol (250 ml) in a Waring Blendor. By means of a De Vilbiss nebulizer the alcoholic extract was sprayed into a bell jar containing two male albino rats. The rats were exposed to a calculated concentration of 41,400 ppm (based on alcohol) for 5.75 hours. Two control rats were exposed to 40,000 ppm alcohol for 5.75 hours. No differences could be detected between the control rats and those exposed to the alcoholic extract of "Teflon"-1 powder, by clinical signs, mortality or gross and micropathological examination. The animals were sacrificed twenty-four hours after exposure.

In the second experiment the same procedure was used except that 300 gm of "Teflon"-1 powder, and 300 ml of alcohol were used and each extraction was for thirty minutes. The two treated rats were exposed to 48,600 ppm alcohol for four hours, while the two control rats were exposed to 46,900 ppm alcohol for four hours. As in the first experiment, no differences could be detected between the control rats and those exposed to the alcoholic extract. The rats were sacrificed and autopsied ten days after exposure.

DISCUSSION

It is of interest to note that the pathological findings with the rats exposed to hexafluoropropylene are similar to findings made in the case of rats exposed to chlorotrifluoroethylene, and when the study of the latter compound was extended to effects on dogs, pronounced neuropathological changes were observed. It is speculative to consider that similar effects might result with hexafluoropropylene, inasmuch as dog studies have not been carried out, but this possibility should be kept in mind.

The results of the acute exposures to the pyrolysis products of "Teflon"-1, "Teflon"-6 and TE-3109 (FST) demonstrate that the hazard is related to the pyrolysis temperature, to the exposure period, and to the quantity of polymer exposed (either surface area or weight) in a given volume of air. However, the hazard does not appear to be related to the weight loss in the polymer. In fact, there were some lethal exposures in which there was no apparent weight loss and in some cases there was an apparent weight gain of the polymer (Runs No. 46 through 49). It may be that the weight loss due to pyrolysis is offset by a weight gain resulting from the reaction of the heated polymer with water and/or oxygen of the air.

It was found that the lethal factor produced in the pyrolysis of "Teflon" at 350°C could not be filtered out by means of a gas scrubber containing 800 ml of water. However, the lethal factor was removed from the air stream by means of Seitz filters, the pore size of which was 0.1, 2 or 5 microns. These results may suggest that particulate matter is associated with or is in fact the lethal factor. Earlier work carried out in this laboratory led to the suggestion that the lethal factor might consist of hydrogen fluoride in association with a "sublimate" (3).

The discovery of the extremely toxic perfluoroisobutylene among the pyrolysis products of "Teflon" has raised a question as to whether it is always the lethal factor. According to Polychemicals Department Report 58-62 (4), however, perfluoroisobutylene could not be detected until "Teflon" was heated above 380°C. Perhaps the analytical procedure used may not have been sufficiently sensitive to detect the very small quantity (0.5 ppm) that is lethal to rats exposed for six hours.

Further experimental work is obviously necessary to determine the nature of the lethal factor resulting from the pyrolysis of "Teflon" below 380°C. Until this is accomplished, a Maximum Acceptable Concentration for the pyrolysis products of "Teflon" cannot be established.

None of the "Teflon" samples tested produced any adverse effects when heated up to 250°C either in the acute or in the subacute exposures. In this respect the "Teflon" samples tested compare very favorably with "Alathon" (polyethylene resin), polyvinyl chloride, and with polyvinyl fluoride. Repeated exposure to fumes from "Alathon"-1 heated at 250°C and acute exposure to fumes from either polyvinyl chloride or polyvinyl fluoride heated at 250°C proved fatal to rats (5, 6).

The experiments with "Teflon" did not reveal any clue as to the nature of the agent causing the "shakes" or "Polymer Fume Fever" in man. So far, neither "polymer fume fever" nor the closely related "metal fume fever" (7, 8) has been produced in experimental animals. However, it is believed that the information and experience gained from these experiments will be of value in future investigations of this problem.

SUMMARY AND CONCLUSIONS

1. Perfluoroisobutylene proved to be an extremely toxic gas. A concentration of 0.5 ppm was lethal for rats exposed for six hours. No cumulative toxicity was found after ten six-hour exposures to 0.1 ppm.

2. Hexafluoropropylene was found to be a moderately toxic gas The approximate lethal concentration for a six-hour period was 735 ppm. The chief pathological change noted at autopsy was kidney damage. This occurred at all levels tested in acute or subacute exposure. Chronic exposure to this gas may be a hazard to health.

3. Carbonyl fluoride was found to be less toxic than perfluoroisobutylene. A concentration of 5 ppm was not lethal for rats exposed for two and one-half hours.

4. The hazard associated with the pyrolysis of "Teflon" was found to be dependent upon the pyrolysis temperature, quantity of polymer, and length of exposure period.

5. Pyrolysis of "Teflon" at 250°C did not produce a harmful atmosphere, while at 300° and at 350°C, lethal atmospheres were produced.

6. Of the three principal "Teflon" products tested, "Teflon"-1 was found to present the least hazard, "Teflon"-6 was intermediate, and TE-3109 (FST) was the most hazardous.

7. Of the other polymeric products tested for hazards associated with pyrolysis, "Fluorofilm", "Fluon", "FST telomerized with Hydrogen" and Poly FEP were found to present no greater toxicity hazards than "Teflon"-1, and less than "Teflon"-6 or TE-3109.

8. The lethal factor resulting from the pyrolysis of "Teflon" below 380°C is still unidentified. As long as this is the case, a Maximum Acceptable Concentration cannot be established for the pyrolysis products of "Teflon."

9. The nature of the factor producing the "shakes" or "Polymer Fume Fever" in man still is undetermined.

REFERENCES

1. Haskell Laboratory Report 1-52, "Progress Report on 'Teflon' Pyrolysis Products, Inhalation Toxicity Tests", MR-220, January 7, 1952.

2. Haskell Laboratory Report 5-54, "Progress Report on 'Teflon' Pyrolysis Products, Inhalation Toxicity Tests", MR-220, April 7, 1954.

3. Haskell Laboratory Report 46-46, "Possible Toxicity of Tetrafluoroethylene and Trifluorochloroethylene", MR-127, October 7, 1946.

4. Polychemicals Department Research Division Report 52-62, "The Toxicity of TFE 'High Boilers' and 'Teflon' Pyrolysis Products", May 13, 1952.

5. Haskell Laboratory Report 11-54, "Inhalation Toxicity of Fumes from 'Alathon' Heated at 250°C, Toxicity of 2-Mercaptobenzimidazole", MR-125, June 14, 1954.

6. Haskell Laboratory, unpublished work.

7. Drinker, K. R. and Drinker, P., "Metal Fume Fever V. Results of the Inhalation by Animals of Zinc and Magnesium Oxide Fumes", J. Ind. Hyg. 10, 56 (1928).

8. Turner, J. A. and Thompson, L. R., "Health Hazards of Brass Foundaries", Public Health Bulletin No. 157, (August, 1925).

HASKELL LABORATORY FOR TOXICOLOGY
AND INDUSTRIAL MEDICINE

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Approved by: D. B. Hood
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Director

GL:ecd
Report No. 18-56
5/4/56

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 18 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

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U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Terry R. O'Bryan
Risk Analysis Branch

Enclosure 12039A

Triage of 8(e) Submissions

Date sent to triage: AUG 2 4 1985

NON-CAP CAP

Submission number: 12039A

TSCA Inventory: Y N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

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ORIGINAL

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entire document: 0 1 2 **pages** 1, 1st tab **pages** 1, all tabs

Notes:

Contractor reviewer : CPS **Date:** 3/10/95

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 88HQ 1092 - 12039 SEQ 1

TYPE: (INT) SUPP FLWP

SUBMITTER NAME: E.I. Dupont de Nemours & Company

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
(0639) REFER TO CHEMICAL SCREENING
(0678) CAP NOTICE

VOLUNTARY ACTIONS:
(0401) NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKER PROTECTION
0404 LAN/LAMSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APPAUSE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

SUB. DATE: 10/15/92 OTS DATE: 10/27/92 CSRAD DATE: 01/25/95

CHEMICAL NAME: none → Teflon, pyrolysis product

Perfluoroisobutylene

CAS#
382-21-8
Mark Dunn
116-15-4
353-50-4

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
0209	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
(0212)	ACUTE TOX. (ANIMAL)	01 (02) 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPI/CLIN	01 02 04
0217	HUMAN EXPOS (PROD CONTAM)	01 02 04
0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04
0219	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECO/AQUA TOX	01 02 04
0221	ENV. OCCC/REL/FATE	01 02 04
0222	EMER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE REQUEST DELAY	01 02 04
(0224)	PROD/COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
0228	ALLERG (ANIMAL)	01 02 04
0239	METAB/PHARMACO (ANIMAL)	01 02 04
0240	METAB/PHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	IMMUNO (ANIMAL)	01 02 04
0242	IMMUNO (HUMAN)	01 02 04
0243	CHEM/PHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
(0248)	PROD/USE/PROC	01 02 04
0251	MSDS	01 02 04
0299	OTHER	01 02 04

4 TOX

TRIAGE DATE:	NON-CBI INVENTORY	ONGOING REVIEW	SPECIES	TOXICOLOGICAL CONCERN:	USE:	PRODUCTION:
	YES	YES (DROP/REFER)	RAT	LOW		
CAS SR	NO	NO (CONTINUE)		MED		
	(DELETE)	REJECT		HIGH		

COMMENTS:

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ 1092 - 12039 SEQ A

TYPE: (INT) SUPP FLWP

SUBMITTER NAME: E. I. Dupont de Nemours & Company

INFORMATION REQUESTED FLWP DATE:
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0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
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(0678) CAP NOTICE

VOLUNTARY ACTIONS
(0401) NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKER/USERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

SUB. DATE: 10/15/92 OTB DATE: 10/29/92 CSRAD DATE: 01/25/95

CHEMICAL NAME: CAS#

Perfluoroisobutylene → none → 382-21-8

Teflon, pyrolysis product → 353-50-4

116-15-4

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0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
(0248)	PROD/USE/PROC	01 02 04
0251	MSDS	01 02 04
0299	OTHER	01 02 04

SBTOX

TRIAGE DATE: NON-CBI INVENTORY: ONGOING REVIEW: SPECIES: TOXICOLOGICAL CONCERN: USE: PRODUCTION:

YES YES (DROP/REFER) RAT (LOW)

CAS SR NO NO (CONTINUE) (MED)

(IN SUMMARY) REVIEW (HIGH)

COMMENTS:

-CPSS-

> <ID NUMBER>
8(E)-12039A

> <TOX CONCERN>
H/L/M/H/L/NLOC/NLOC/NLOC/NLOC/NLOC/NLOC/NLOC/NLOC/NLOC/L

> <COMMENT> H/G-14
PERFLUOROISOBUTYLENE: ACUTE INHALATION TOXICITY IN MALE ALBINO RATS IS OF ~~LOW~~ CONCERN. SINGLE WHOLE-BODY EXPOSURES TO 0.3 AND 0.5 PPM EACH FOR 6 HOURS TO 2 MALE RATS ESTABLISHED 0.5 PPM X 6 HOURS AS A LETHAL EXPOSURE UPON THE DEATH OF BOTH ANIMALS DURING THE EXPOSURE; NEITHER ANIMAL OF A 0.3 PPM, 6-HOUR EXPOSURE DIED.

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PERFLUOROISOBUTYLENE: SUBACUTE INHALATION TOXICITY IN MALE ALBINO RATS IS OF LOW CONCERN. WHOLE-BODY EXPOSURES OF 0.1 PPM FOR 6 HOURS PER DAY FOR 10 DAYS WAS ASSOCIATED WITH NO MORTALITY IN 2 MALE ALBINO RATS. NO ACCUMULATED SYSTEMIC TOXICITY WAS DISCERNED FROM CLINICAL OBSERVATION, BODY OR ORGAN WEIGHT ANOMALIES, OR GROSS AND MICROPATHOLOGICAL EVALUATION.

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HEXAFLUOROPROPYLENE: ACUTE INHALATION TOXICITY IN MALE ALBINO RATS IS OF MEDIUM CONCERN. SINGLE WHOLE-BODY EXPOSURES OF 600 PPM AND 755 PPM EACH FOR 6 HOURS TO 2 MALE RATS ESTABLISHED 755 PPM X 6 HOURS AS A LETHAL EXPOSURE UPON THE DEATH OF BOTH ANIMALS DURING THE EXPOSURE; NEITHER ANIMAL OF A 600 PPM, 6-HOUR EXPOSURE DIED. EXPOSURE TO BOTH LEVELS FOR 6 HOURS WERE ASSOCIATED WITH KIDNEY DAMAGE. NO SPECIFIC DATA WERE PROVIDED.

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HEXAFLUOROPROPYLENE: SUBACUTE INHALATION TOXICITY IN MALE ALBINO RATS IS OF HIGH CONCERN. WHOLE-BODY EXPOSURES TO 220 PPM FOR 6 HOURS PER DAY FOR TEN DAYS WAS LETHAL IN 2/4 ANIMALS FOLLOWING A 4TH EXPOSURE. CUMULATIVE SYSTEMIC TOXICITY WAS DEMONSTRATED IN THE 2/4 SURVIVORS OF 10 6-HOUR EXPOSURES IN ENLARGED KIDNEYS WITH TUBULAR NEPHRITIS OBSERVED UPON TERMINAL POSTTREATMENT NECROPSY.

.

CARBONYL FLUORIDE: ACUTE INHALATION TOXICITY IN MALE ALBINO RATS IS OF LOW CONCERN. SINGLE WHOLE-BODY EXPOSURES TO 3 PPM FOR 2-1/2 HOURS IN 2 MALE RATS WERE ASSOCIATED WITH NO MORTALITY. NEITHER WAS ANY ORGAN-SPECIFIC TOXICITY DEMONSTRATED UPON GROSS- OR HISTOPATHOLOGICAL EVALUATION.

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TE-3109 (FST) PYROLYSIS PRODUCTS: ACUTE INHALATION TOXICITY IN MALE ALBINO RATS IS ASSIGNED NO LEVEL OF CONCERN. SINGLE WHOLE-BODY EXPOSURES TO THE PYROLYSIS PRODUCTS PRODUCED BY 16,000 SQ MM OF THE POLYMER HEATED TO TEMPERATURES OF 200, 250, 300 AND 350 DEGREES FOR 6 HOURS IN 2 MALE RATS WERE ASSOCIATED WITH NO TOXIC EFFECTS OR MORTALITY AT TEMPERATURES OF 200 OR 250 DEGREES. MORTALITY AND CLINICAL DATA FROM EXPOSURES TO HIGHER-TEMPERATURE PRODUCTS ESTABLISHED TE-3109 PYROLYSIS PRODUCTS AS MORE TOXIC THAN THOSE OF "TEFLON"-6 OR "TEFLON"-1. LETHALITY WAS ASSOCIATED WITH PULMONARY EDEMA AT TEMPERATURES OF 300 DEGREES AND ABOVE. FILTRATION OF

"TEFLON" PYROLYSIS PRODUCTS AT 350 DEGREES THROUGH 0.1 MICRON MESH PRIOR TO DELIVERY IN BELL JAR EFFECTIVELY REMOVED THE TOXIC SUBSTANCE, AS EVIDENCED BY THE ABSENCE OF TOXIC RESPONSE IN 2 RATS. FILTRATION WITH MESH OF 2 OR 5 MICRONS WERE NOT EFFECTIVE IN REMOVING THE TOXIC ENTITY AS THE 1 MICRON MESH WAS INEFFECTIVE IN FILTERING OUT THE TOXIC FACTOR OF "TEFLON" PYROLYSIS PRODUCTS AT 450-500 DEGREES. SPECIFIC DATA WERE NOT PROVIDED.

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"TEFLON"-6 PYROLYSIS PRODUCTS: ACUTE INHALATION TOXICITY IN MALE ALBINO RATS IS ASSIGNED NO LEVEL OF CONCERN. SINGLE WHOLE-BODY EXPOSURES TO THE PYROLYSIS PRODUCTS PRODUCED BY 16,000 SQ MM OF THE POLYMER HEATED TO TEMPERATURES OF 200, 250, 300 AND 350 DEGREES FOR 6 HOURS IN 2 MALE RATS ESTABLISHED THAT "TEFLON"-6 PYROLYSIS PRODUCTS ARE LESS TOXIC THAN THOSE OF TE-3109 AND MORE TOXIC THAN THOSE OF "TEFLON"-1. NO TOXIC EFFECTS WERE ELICITED FROM EXPOSURES TO THE PRODUCTS OF 200 OR 250 DEGREE TEMPERATURES. NO OTHER DATA REGARDING MORTALITY OR CLINICAL OBSERVATION WERE PROVIDED. LETHALITY WAS ASSOCIATED WITH PULMONARY EDEMA AT TEMPERATURES OF 300 DEGREES AND ABOVE. FILTRATION OF "TEFLON" PYROLYSIS PRODUCTS AT 350 DEGREES THROUGH 0.1 MICRON MESH PRIOR TO DELIVERY IN BELL JAR EFFECTIVELY REMOVED THE TOXIC SUBSTANCE, AS EVIDENCED BY THE ABSENCE OF A TOXIC RESPONSE IN 2 RATS. FILTRATION WITH MESH OF 2 OR 5 MICRONS WERE NOT EFFECTIVE IN REMOVING THE TOXIC ENTITY AS THE 1 MICRON MESH WAS INEFFECTIVE IN FILTERING OUT THE TOXIC FACTOR OF "TEFLON" PYROLYSIS PRODUCTS AT 450-500 DEGREES. SPECIFIC DATA WERE NOT PROVIDED.

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"TEFLON"-1 PYROLYSIS PRODUCTS: ACUTE INHALATION TOXICITY IN MALE ALBINO RATS IS ASSIGNED NO LEVEL OF CONCERN. SINGLE WHOLE-BODY EXPOSURES TO THE PYROLYSIS PRODUCTS PRODUCED BY 16,000 SQ MM OF THE POLYMER HEATED TO TEMPERATURES OF 200, 250, 300 AND 350 DEGREES FOR 6 HOURS IN 2 MALE RATS ESTABLISHED THAT "TEFLON"-1 PYROLYSIS PRODUCTS ARE LESS TOXIC THAN THOSE OF TE-3109 OR "TEFLON"-6. NO TOXIC EFFECTS WERE ELICITED FROM EXPOSURES TO THE PRODUCTS OF 200 OR 250 DEGREE TEMPERATURES. LETHALITY WAS ASSOCIATED WITH PULMONARY EDEMA AT TEMPERATURES OF 300 DEGREES AND ABOVE. FILTRATION OF "TEFLON" PYROLYSIS PRODUCTS AT 350 DEGREES THROUGH 0.1 MICRON MESH PRIOR TO DELIVERY IN BELL JAR EFFECTIVELY REMOVED THE TOXIC SUBSTANCE, AS EVIDENCED BY THE ABSENCE OF TOXIC RESPONSE IN 2 RATS. FILTRATION WITH MESH OF 2 OR 5 MICRONS WERE NOT EFFECTIVE IN REMOVING THE TOXIC ENTITY AS THE 1 MICRON MESH WAS INEFFECTIVE IN FILTERING OUT THE TOXIC FACTOR OF "TEFLON" PYROLYSIS PRODUCTS AT 450-500 DEGREES. SPECIFIC DATA WERE NOT PROVIDED.

.

"FLUOROFILM" B PYROLYSIS PRODUCTS: ACUTE INHALATION TOXICITY IN MALE ALBINO RATS IS ASSIGNED NO LEVEL OF CONCERN. SINGLE WHOLE-BODY EXPOSURES TO THE PYROLYSIS PRODUCTS PRODUCED BY 16,000 SQ MM OF THE POLYMER HEATED TO TEMPERATURES OF 200, 250, 300 AND 350 DEGREES FOR 6 HOURS IN 2 MALE RATS ESTABLISHED THAT "FLUOROFILM" B PYROLYSIS PRODUCTS PRESENT A SIMILAR TOXICOLOGICAL HAZARD TO THAT OF "TEFLON"-1 AND A LESSER HAZARD THAN THAT OF EITHER TE-3109 OR "TEFLON"-6. NO TOXIC EFFECTS WERE ELICITED FROM EXPOSURES TO THE PRODUCTS OF 200 OR 250 DEGREE TEMPERATURES. LETHALITY WAS ASSOCIATED WITH PULMONARY EDEMA AT TEMPERATURES OF 300 DEGREES AND

ABOVE. MANIPULATION OF RELATIVE HUMIDITY (95 TO 30 PERCENT) OF THE AIR FLOW AT 25 DEGREES CENTIGRADE, WHICH DELIVERED PYROLYSIS VAPOR PRODUCTS TO 2 RATS, DID NOT ALTER THE TOXIC EFFECT.

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POLY PEP B PYROLYSIS PRODUCTS: ACUTE INHALATION TOXICITY IN MALE ALBINO RATS IS ASSIGNED NO LEVEL OF CONCERN. SINGLE WHOLE-BODY EXPOSURES TO THE PYROLYSIS PRODUCTS PRODUCED BY 16,000 SQ MM OF THE POLYMER HEATED TO TEMPERATURES OF 200, 250, 300 AND 350 DEGREES FOR 6 HOURS IN 2 MALE RATS ESTABLISHED THAT POLY PEP B PYROLYSIS PRODUCTS PRESENT A SIMILAR TOXICOLOGICAL HAZARD TO THAT OF "TEFLON"-1 AND A LESSER HAZARD THAN THAT OF EITHER TE-3109 OR "TEFLON"-6. NO TOXIC EFFECTS WERE ELICITED FROM EXPOSURES TO THE PRODUCTS OF 200 OR 250 DEGREE TEMPERATURES. LETHALITY WAS ASSOCIATED WITH PULMONARY EDEMA AT TEMPERATURES OF 300 DEGREES AND ABOVE. MANIPULATION OF RELATIVE HUMIDITY (95 TO 30 PERCENT) OF THE AIR FLOW AT 25 DEGREES CENTIGRADE, WHICH DELIVERED PYROLYSIS VAPOR PRODUCTS TO 2 RATS, DID NOT ALTER THE TOXIC EFFECT.

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FST (H2) B PYROLYSIS PRODUCTS: ACUTE INHALATION TOXICITY IN MALE ALBINO RATS IS ASSIGNED NO LEVEL OF CONCERN. SINGLE WHOLE-BODY EXPOSURES TO THE PYROLYSIS PRODUCTS PRODUCED BY 16,000 SQ MM OF THE POLYMER HEATED TO TEMPERATURES OF 200, 250, 300 AND 350 DEGREES FOR 6 HOURS IN 2 MALE RATS ESTABLISHED THAT FST (H2) PYROLYSIS PRODUCTS PRESENT A SIMILAR TOXICOLOGICAL HAZARD TO THAT OF "TEFLON"-1 AND A LESSER HAZARD THAN THAT OF EITHER TE-3109 OR "TEFLON"-6. NO TOXIC EFFECTS WERE ELICITED FROM EXPOSURES TO THE PRODUCTS OF 200 OR 250 DEGREE TEMPERATURES. NO OTHER DATA REGARDING MORTALITY OR CLINICAL OBSERVATIONS WERE PROVIDED. LETHALITY WAS ASSOCIATED WITH PULMONARY EDEMA AT TEMPERATURES OF 300 DEGREES AND ABOVE. MANIPULATION OF RELATIVE HUMIDITY (FROM 95 TO 30 PERCENT) OF THE AIR FLOW AT 25 DEGREES CENTIGRADE, WHICH DELIVERED PYROLYSIS VAPOR PRODUCTS TO 2 RATS, DID NOT ALTER THE TOXIC EFFECT.

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"FLUON" B PYROLYSIS PRODUCTS: ACUTE INHALATION TOXICITY IN MALE ALBINO RATS IS ASSIGNED NO LEVEL OF CONCERN. SINGLE WHOLE-BODY EXPOSURES TO THE PYROLYSIS PRODUCTS PRODUCED BY 16,000 SQ MM OF THE POLYMER HEATED TO TEMPERATURES OF 200, 250, 300 AND 350 DEGREES FOR 6 HOURS IN 2 MALE RATS ESTABLISHED THAT "FLUON" B PYROLYSIS PRODUCTS PRESENT A SIMILAR TOXICOLOGICAL HAZARD TO THAT OF "TEFLON"-1 AND A LESSER HAZARD THAN THAT OF EITHER TE-3109 OR "TEFLON"-6. NO TOXIC EFFECTS WERE ELICITED FROM EXPOSURES TO THE PRODUCTS OF 200 OR 250 DEGREE TEMPERATURES. NO OTHER DATA REGARDING MORTALITY OR CLINICAL OBSERVATION WERE PROVIDED. LETHALITY WAS ASSOCIATED WITH PULMONARY EDEMA AT TEMPERATURES OF 300 DEGREES AND ABOVE. MANIPULATION OF RELATIVE HUMIDITY (FROM 95 TO 30 PERCENT) OF THE AIR FLOW AT 25 DEGREES CENTIGRADE, WHICH DELIVERED PYROLYSIS VAPOR PRODUCTS TO 2 RATS, DID NOT ALTER THE TOXIC EFFECT.

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"KEL-F" B PYROLYSIS PRODUCTS: ACUTE INHALATION TOXICITY IN MALE ALBINO RATS IS ASSIGNED NO LEVEL OF CONCERN. SINGLE WHOLE-BODY EXPOSURES TO THE PYROLYSIS PRODUCTS PRODUCED BY 16,000 SQ MM OF THE POLYMER HEATED TO TEMPERATURES OF 200, 250, 300 AND 350 DEGREES FOR 6 HOURS IN 2 MALE RATS ESTABLISHED THAT "KEL-F" B PYROLYSIS PRODUCTS PRESENT A GREATER TOXICOLOGICAL HAZARD THAN THAT OF EITHER

TE-3109, "TEFLON"-1 OR "TEFLON"-6. NO TOXIC EFFECTS WERE ELICITED FROM EXPOSURES TO THE PRODUCTS OF 200 OR 250 DEGREE TEMPERATURES. LETHALITY WAS ASSOCIATED WITH PULMONARY EDEMA AT TEMPERATURES OF 300 DEGREES AND ABOVE. NO OTHER DATA REGARDING MORTALITY OR CLINICAL OBSERVATION WERE PROVIDED. MANIPULATION OF RELATIVE HUMIDITY (FROM 95 TO 30 PERCENT) OF THE AIR FLOW AT 25 DEGREES CENTIGRADE, WHICH DELIVERED PYROLYSIS VAPOR PRODUCTS TO 2 RATS, DID NOT ALTER THE TOXIC EFFECT.

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"FLUOROFILM" B PYROLYSIS PRODUCTS: SUBACUTE INHALATION TOXICITY IN MALE ALBINO RATS IS ASSIGNED NO LEVEL OF CONCERN. WHOLE-BODY EXPOSURES TO THE PYROLYSIS PRODUCTS PRODUCED BY 16,000 SQ MM OF THE POLYMER HEATED TO TEMPERATURES OF 250 DEGREES FOR 7 HOURS PER DAY, 5 DAYS PER WEEK FOR 30 DAYS, AT A CONSTANT 95 PERCENT RELATIVE HUMIDITY WERE ASSOCIATED WITH NO SIGNS OF CUMULATIVE SYSTEMIC TOXICITY OR MORTALITY: CLINICAL SIGNS, GROWTH RATE, ORGAN WEIGHTS, GROSS AND MICROPATHOLOGICAL EXAMINATIONS REVEALED NO TREATMENT-RELATED ANOMALIES. WEIGHT LOSS WAS NOTED FOLLOWING A FIRST EXPOSURE ONLY. NO OTHER DATA WERE PROVIDED.

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"TEFLON"-5 PYROLYSIS PRODUCTS: SUBACUTE INHALATION TOXICITY IN MALE ALBINO RATS IS ASSIGNED NO LEVEL OF CONCERN. WHOLE-BODY EXPOSURES TO THE PYROLYSIS PRODUCTS PRODUCED BY 16,000 SQ MM OF THE POLYMER HEATED TO TEMPERATURES OF 250 DEGREES FOR 7 HOURS PER DAY, 5 DAYS PER WEEK FOR 30 DAYS, AT A CONSTANT 95 PERCENT RELATIVE HUMIDITY WERE ASSOCIATED WITH NO SIGNS OF CUMULATIVE SYSTEMIC TOXICITY OR MORTALITY: CLINICAL SIGNS, GROWTH RATE, ORGAN WEIGHTS, GROSS AND MICROPATHOLOGICAL EXAMINATIONS REVEALED NO TREATMENT-RELATED ANOMALIES. WEIGHT LOSS WAS NOTED FOLLOWING A FIRST EXPOSURE AND OCCURRED UNIFORMLY FOLLOWING SUBSEQUENT EXPOSURES. NO OTHER DATA WERE PROVIDED.

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"TEFLON"-1 ALCOHOLIC EXTRACT: ACUTE INHALATION TOXICITY OF THE ALCOHOL EXTRACTION PRODUCTS OF "TEFLON"-1 IN MALE ALBINO RATS IS OF LOW CONCERN. SINGLE WHOLE-BODY EXPOSURES TO THE PRODUCTS OF 5-MINUTE, 250 ML ABSOLUTE ETHYL ALCOHOL EXTRACTION OF 200 G "TEFLON"1 POWDER AT 41,400 PPM FOR 5.75 HOURS IN 2 MALE RATS WERE ASSOCIATED WITH NO TOXICITY RELATIVE TO CONTROL ANIMALS EXPOSED TO 40,000 PPM ALCOHOL ALONE: NO SYSTEMIC TOXICITY COULD BE DEMONSTRATED UPON EVALUATION OF CLINICAL SIGNS, MORTALITY OR GROSS AND MICROPATHOLOGY. PRODUCTS OF 30-MINUTE ALCOHOL EXTRACTION OF 300 G "TEFLON"-1 WITH 300 ML ALCOHOL SUPPLIED FOR 4 HOURS BY NEBULIZER TO 2 RATS AT 46,900 PPM LIKEWISE PRODUCED NO DISTINCT TOXIC EFFECT RELATIVE TO CONTROL. NO SPECIFIC DATA WERE PROVIDED.

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